OCT 1 7 2000

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Section 2

510(k) Summary of Safety and Effectiveness

K002420
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1.0 Submitter Information

1.1 Submitter: Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, Ohio 44080-2371
ph: (330) 425-1313
fax: (330) 425-1410

1.2 Contact: Douglas J. Thistlethwaite

1.3 Date: August 7, 2000

2.0 Device Name

2.1 Classification Name: System, Nuclear Magnetic Resonance Imaging

2.2 Classification Number: 90LNH

2.3 Trade/Proprietary Name: ALTAIRE Magnetic Resonance Imaging System

2.4 Predicate Device(s): Hitachi AIRIS II MRI System (K001334)
GE Signa OpenSpeed MRI System (K992746)

3.0 Device Intended Use

The MR system is an imaging device and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

4.0 Device Description

4.1 Function

The ALTAIRE is a Magnetic Resonance Imaging System that utilizes a 0.7 Tesla superconducting magnet in an open gantry design. The design was based on the AIRIS II Open MRI system. The ALTAIRE has been designed to enhance clinical utility as compared to the AIRIS II by taking advantage of the imaging properties of the 0.7T magnet.

4.2 Scientific Concepts

Magnetic Resonance Imaging (MRI) is based on the fact that certain atomic nuclei have electromagnetic properties that cause them to act as small spinning bar magnets. The most ubiquitous of these nuclei is hydrogen, which makes it the primary nuclei currently used in magnetic resonance imaging. When placed in a static magnetic field, these nuclei assume a net orientation or alignment with the magnetic field, referred to as a net magnetization vector. The introduction of a short burst of radiofrequency (RF) excitation of a wavelength specific to the magnetic field strength and to the atomic nuclei under consideration can cause a re-orientation of the net magnetization vector. When the RF excitation is removed, the protons relax and return to their original vector. The rate of relaxation is exponential and varies with the character of the proton and its adjacent molecular environment. This re-orientation process is characterized by two exponential relaxation times, called T1 and T2.

A RF emission or echo that can be measured accompanies these relaxation events. The emissions are used to develop a representation of the relaxation events in a three dimensional matrix. Spatial localization is encoded into the echoes by varying the RF excitation, applying appropriate magnetic field gradients in the x, y, and z directions, and changing the direction and strength of these gradients. Images depicting the spatial distribution of the NMR characteristics can be reconstructed by using image processing techniques similar to those used in computed tomography.

4.3 Physical and Performance Characteristics

MRI is currently of great interest because it is capable of producing high quality anatomical images without the associated risks of ionizing radiation. The biological properties that contribute to MR image contrast are different from those responsible for x-ray image contrast. In MR imaging, difference in proton density, blood flow, and T1 and T2 relaxation times can all contribute to image contrast. By varying the pulse sequence characteristics, the resulting images can emphasize T1, T2, proton density, or the molecular diffusion of water or other proton containing molecules.

5.0 Device Technological Characteristics

The technological characteristics of this device are similar to the primary predicate device. The primary difference is the higher magnetic field strength. The RF and gradient sub-systems are also enhanced. The control and image processing hardware and the base elements of the operating system software are identical to the primary predicate device.

6.0 Conclusions

It is the opinion of Hitachi Medical Systems America that ALTAIRE MRI system is substantially equivalent to the listed predicate devices. The intended use is identical to the listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2000

Doug Thistlethwaite
Manager, Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, Ohio 44087

Re: K002420
Altaire (Magnetic Resonance Imaging Device)
Dated: August 7, 2000
Received: August 8, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Thistlethwaite:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use ~~stated in the enclosure~~) to legally ~~marketed predicate~~ devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration ~~(FDA) will~~ verify such assumptions. ~~Failure~~ to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K00 2420

Device Name: Altaire MRDD, w/V4.3 Operating System Software

Indications for Use:

The MR system is an imaging device, and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

Anatomical Region:	Head, Body, Spine, Extremities
Nucleus excited:	Proton
Diagnostic uses:	T1, T2, proton density weighted imaging
	Diffusion weighted imaging
	MR Angiography
	Image processing
Imaging capabilities:	2D, 3D Spin Echo (SE)* *with re-phasing
	2D, 3D Fast Spin Echo (FSE)*, Fast Inversion Recovery (FIR)*
	2D Inversion Recovery (IR)*
	2D, 3D Gradient Field Echo (GE)*
	2D, 3D Steady State Acquisition with Rewinded GE (SARGE™)*
	2D, 3D RF-spoiled SARGE (RSSG)*
	2D, 3D Time-reversed SARGE (TRSG)*
	2D, 3D Spin Echo-Echo Planar Imaging (SE-EPI)
	2D, 3D Gradient Echo-Echo Planar Imaging (GE-EPI)
	MR Angiography*
	Half echo, high resolution/high definition, sloped slab profile, magnetization transfer contrast, 2D/3D TOF, 2D/3D TOF RSSG, Contrast Enhanced
	ECG, Peripheral, and Respiratory Gating
	MR Fluoroscopy
	RF Coil Uniformity
	Adaptive Image post-processing
	ACR/NEMA/DICOM 3 compliant
	RF fat saturation
	Fat/Water Separation

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002420

Prescription Use ✓ OR Over-the-Counter Use _____